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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,928	08/27/2002	Edward Burton	HO-P02428USO	1211

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EXAMINER
KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,928	BURTON ET AL.	
	Examiner	Art Unit	
	Konstantina Katcheves	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *53-111* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Claims 53-111 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 53-70 and 77-91, drawn to an isolated nucleic acid comprising human promoter sequence of SEQ ID NO:1 or the mouse promoter seqeuence of SEQ ID NO:3, a host cell comprising said sequence, and a method of using the sequence, classified in class 536, subclass 24.1.

II. Claims 71-76, drawn to a method of screening for a substante, classified in class 435, subclass 6.

III. Claims 92-98, drawn to an isolated polypeptide encoded by the either the sequence of SEQ ID NO:2 or SEQ ID NO:4, classified in class 530, subclass 350.

IV. Claim 99, drawn to an antibody, classified in class 424, subclass 130.1.

V. Claims 100-103, drawn to a pharmaceutical composition comprising a peptide, classified in class 424, subclass 184.1.

VI. Claim 104 and 111, drawn to a pharmaceutical composition comprising an antibody and method of using said antibody, classified in class 424, subclass 130.1.

VII. Claims 105 and 106, drawn to a method for treating dystrophin phenotype comprising administering a nucleotide in a therapeutically effective amount, classified in class 514, subclass 44.

VII. Claims 107-110, drawn to a method for treating dystrophin phenotype comprising administering a polypeptide in a therapeutically effective amount, classified in class 514, subclass 44.

Groups I, III, V, VII and VIII are further restricted to one nucleic acid and/or amino acid sequence recited in the claims for the following reasons. This application contains claims directed to patentably distinct species, *i.e.* sequences, of the claimed invention. The nucleotide sequences and amino acid sequences of the instant claims are subject to a restriction requirement. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These nucleic acid and protein sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence or amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Accordingly, in most cases, only one (1) independent and distinct sequence will be examined in a single application without restriction.

The nucleic acid of Group I, the polypeptide of Group III, the antibody of Group IV , the peptide pharmaceutical composition of Group V, and the antibody pharmaceutical composition of Group VI are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The polypeptide of Group III is not required to produce the nucleic acid sequence of Group I because the nucleic acid sequence is not required to produce the polypeptide which can be produced synthetically or isolated from cells. The polypeptide is not required to produce the polynucleotide of Group I which can be replicated in vectors without the use of the protein. Additionally, the antibody of Group IV can be produced separately in a

host organism or isolated from a host and does not require the use of the other products of the claims. The polypeptide and antibody pharmaceutical compositions also are separate and distinct from the other products of the claims and each other because pharmaceutical composition have unique and necessary excipients and different considerations of safety and efficacy are required for each of these two groups that are not required for the others.

Inventions of Groups I, II, VII and VIII are biologically and functionally different and distinct methods from each other and thus one does not render the other obvious. The methods of Groups I, II, and VII comprise steps which are not required for or present in the methods of the other groups: culturing a host cell and the expression of a construct (Group I), contacting a cell with a test or candidate substance and determining transcription (Group II), administration of a comprising administering a nucleic acid (Group VII), administration of a polypeptide or polypeptide fragment (Group VIII). Thus, the operation, function and effects of these different methods are different and distinct from each other. Moreover, the end results of each of these methods differ. For example, Group I involves the expression of a nucleic acid construct; Group II involves determining if a candidate or test substance has an effect on a cell; Group VII involves treatment with a nucleic acid construct, i.e. gene therapy; and Group VIII involves treatment with a polypeptide. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and the search required for each of the above groups is not required for each of the others, restriction for examination purposes as indicated is proper. A separate search strategy, different databases, and separate

execution of each search is required for each of the above groups such that a serious search burden is presented to the examiner.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves
Examiner
Art Unit 1636

JAMES KETTER
PRIMARY EXAMINER